

REMARKS/ARGUMENTS

Claims 85, 94, 95, 105, 106, 116, 119, 128, 129, and 138 have been amended to more fully describe the present invention. Claims 93, 103-104, 114-115, 127 and 137 have been canceled. Claims 85-92, 94-102, 105-113, 116-126, 128-136 and 138 remain pending in the application.

Claims 85-138 stand provisionally rejected under 35 U.S.C. 101 over claims 64-117 of copending Application No. 09/897,753 and claims 85-116 and 120-138 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 2-7, 10-16, 18-23 and 25-30 of copending Application No. 09/606,909. Inasmuch as neither of the cited patent applications has issued, Applicant requests that these provisional rejections be deferred at this time.

Reconsideration and withdrawal of the rejection of Claims 85-116 and 119-138 under 35 U.S.C. 102(e) over Pettis et al. (US2002/0095134) ('134) is requested because the cited reference was filed on June 29, 2001, the same filing date as the instant application. Thus, the '134 application was not filed before the invention by the applicant as required under 102(e)(1).

It is noted that the '134 application claims priority to 09/606,909, filed June 29, 2000 in the first paragraph of the specification. A copy of the 09/696,909 application has been provided in response to the prior Office Action and Information Disclosure Statement both of which were submitted February 28, 2003. The '909 application, however, does not contain the passages cited by the Examiner in the '134 application. The rejection is, thus, believed to be improper and withdrawal is, respectfully, requested.

Reconsideration and withdrawal of the rejection of Claims 85, 86, 90-98, 102-109, 113-116, 120, 124-130 and 134-138 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,848,991 to Gross et al. is requested because the cited reference fails to disclose, either expressly or inherently, each and every element of the invention as

claimed. *Schering Corp. v. Geneva Pharmaceuticals Inc.*, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, *Schering Corp. v. Geneva Pharmaceuticals Inc.*, 814 F.2d 628, 631, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). The claims of the instant application as amended, recite injecting the substance into the dermis by “bolus administration”. Bolus administration is understood in the art to mean rapid injection (see, for example, paragraphs 18 and 21 of the instant application). In contrast, the ‘991 fails to disclose injection by bolus administration, but, instead, teaches administration by slow infusion, stating “[t]he device permits delivery of drugs of relatively large molecular size and at slow rates which can be precisely controlled” Abstract, Ins. 13-15 (emphasis added). (see also Col. 2, Ins. 22-25; Col. 4, Ins. 29-35; Col. 7, Ins. 47-49). Thus, the ‘991 reference fails to disclose or suggest each and every element of the invention as claimed and withdrawal of the rejection is, therefore, requested.

Reconsideration of the rejection of Claims 117-119 under 35 U.S.C. 102(a) as being anticipated by WO/01/13989 to Sun et al. ('989) is requested because the reference fails to teach or suggest a method of administration involving injecting a substance into the dermis as claimed. In contrast, the '989 reference teaches a drug delivery method involving the production of pores in the stratum corneum which is the outer layer of the epidermis (see page 4, Ins. 25-30; page 26, Ins. 26-28; page 29, Ins. 8-11). This results in delivery to the epidermis and not to the dermis as recited in the claims of the instant application. This is further stated in the '989 reference in that “[f]or example, stratum corneum perforation may be suitable for transdermal drug delivery, while perforation through the epidermis, or even some part of dermis, may be suitable for interstitial fluid

sampling or vaccination." (page 39, line 32 through page 40, line 3). Thus, the reference teaches drug delivery to the epidermis and deeper perforation for fluid sampling or vaccination which involves a localized delivery and not systemic delivery of a substance. Hence, the '989 reference neither discloses nor suggests selective deliver of a substance into the dermis to obtain systemic absorption as claimed in the instant application.

Withdrawal of the rejection is, therefore, requested.

Reconsideration of the rejection of Claims 85-88, 90, 91, 93-100, 103-111, 114-116, 119-122, 124, 125, 127-132 and 134-138 under 35 U.S.C. 103(a) over Alchas because the reference fails to suggest the invention as claimed. Applicant believes that the Alchas reference cited by the U.S.P.T.O. is intended to mean U.S. Patent No. 6,494,864 to Alchas ('864) which is listed in the Notice of References Cited, Form PTO-892. Nevertheless, this reference does not list "[b]ioactivities for incorporation" at col. 5 or anywhere else in the reference, nor does this reference disclose "dopamine agonists and antagonists, growth hormone, and low molecular weight heparin" as stated by the U.S.P.T.O (Office Action dated 09/09/2003, page 6, last paragraph, lines 3-4). Thus, this reference fails to disclose or suggest administration of a growth hormone, a low molecular weight heparin or a dopamine receptor agonist as claimed.

Furthermore, the '864 patent does not disclose or suggest administration to the dermis by bolus, i.e. rapid administration (see paragraphs 18 and 22 of the instant application). Instead this reference refers to "injection" (see, for example, Abstract, Col. 1, lns. 12-13; Col. 1, ln. 64; Col. 2, lns. 13-27) without reference to any rate of delivery. The term "injection" merely means "to introduce (as by injection or gravity flow) a fluid into (a living body)" and nothing more (see Webster's Third New International

Dictionary of the English Language Unabridged, Philip Babcock gove, Ph.D. Ed., Merriam-Webster Inc., Springfield, Massachusetts, 1993, page 1164).

Furthermore, the statement by the U.S.P.T.O. that “[t]he increased bioavailability over subcutaneous administration is an inherent property of the method of administration” is meaningless without reference to a rate of administration. Indeed, an increase in absorption compared to that obtained following subcutaneous administration is seen after bolus administration as claimed, but little or not detectable improvement is seen following administration by infusion. This is illustrated in Figure 8 of the instant application, where it is shown that increased levels of Fragmin are achieved following bolus administration into the dermis in comparison to that achieved following bolus subcutaneous administration, whereas in Figure 10, it is shown that there is little or no difference in the levels achieved following administration by infusion into the dermis or infusion subcutaneously. In that regard, the ‘864 fails to disclose or even suggest this absorption advantage achieved upon rapid administration by bolus into the dermis compared to absorption achieved upon bolus administration subcutaneously.

Because the ‘864 reference fails to teach or suggest administration of a growth hormone, a low molecular weight heparin or a dopamine receptor agonist and, furthermore, because this reference fails to teach or suggest rapid administration by bolus, the rejection under 35 U.S.C. 103(a) is not believed to be supported by the cited reference (see *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 164; 225 USPQ 34, 38 (Fed. Cir. 1985)). Withdrawal of the rejection is, therefore, requested.

It is believed that the claims are in a condition for allowance and such favorable action is requested. Should any questions arise, the U.S.P.T.O. is requested to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, reading "Donald R. Holland". The signature is written in a cursive style with a large, looping initial "D".

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